



Australian Government  
Department of Health  
Therapeutic Goods Administration

# Consumer Medicine Information

Improving the CMI template

**Dr Grant Pegg**

Director – Signal Investigation Unit

Pharmacovigilance and Special Access Branch

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**TGA** Health Safety  
Regulation

# Objectives

- A revised, improved CMI template
- Reduce complexity and improve readability
- Evidence-based changes

# Context

- Widely acknowledged issues with current format
- I-CMI Project
- Electronic Distribution Working Group (EDWG)
- Letters to peak industry and health professional bodies from Minister Hunt (January 2019)

# Activities

- Stakeholder workshop
- Development of the draft revised template
  - three examples developed by EDWG (a tablet, an inhaler and an injectable)
- Usability testing
  - ThinkPlace (digital) and Prof Parisa Aslani, USyd (print)
  - iterative improvements over the three rounds of testing
- Final workshop

# What was user tested?

- Summary page
- Two columns and reverse contrast headings
  - Better use of white space and less bolding
- Tabulated side effects
  - Minor and serious
- Minimal content changes

# User testing results

- Users overwhelmingly preferred the new format
  - complexity reduced and readability improved
- Summary rated positively
- Improved findability of information
  - reduced content, better layout and use of tables
- Process-based headings were confusing
  - topic-based headings were better

# User testing results

- Complex/unfamiliar terminology must be explained
- Calls-to-action should be direct, unambiguous and consistently displayed
- Digital format
  - single-column layout was better due to need for scrolling
  - opportunities for future enhancements

# What now?

- Final report and template
  - to be published on the TGA website
  - will be supported by instructions on how to use it and tips for writing content
- Ministerial announcement



## [medicine name]\*

### Consumer Medicine Information (CMI) summary Important information about your medicine

This page contains the most important points from the Consumer Medicine Information (CMI).  
The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

#### 1. Why am I using [medicine name]?

[Medicine name] contains the active ingredient [insert active ingredient]. [Medicine name] is used to .....  
For more information, see Section 1. [Why am I using \[medicine name\]?](#) in the full CMI.

#### 2. What should I know before I use [medicine name]?

Do not use it if you have ever had an allergic reaction to [medicine] or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you:

- have any other medical conditions
- take any medicines for any other medical condition
- are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. [What should I know before I use \[medicine name\]?](#) in the full CMI.

#### 3. What if I am taking other medicines?

Some medicines may interfere with [medicine name] and affect how it works.  
A list of these medicines is in Section 3. [What if I am taking other medicines?](#) in the full CMI.

#### 4. How do I use [medicine name]?

- [Insert statement regarding dosage]
- [Insert statement(s) regarding device use / other important directions for use]

More instructions can be found in Section 4. [How do I use \[medicine name\]?](#) in the full CMI.

#### 5. What should I know while using [medicine name]?

<b>Things you should do</b>	<ul style="list-style-type: none"> <li>• Remind any doctor or dentist you visit that you are using [insert medicine].</li> <li>• [Insert other relevant key point(s) e.g. monitoring of the condition / effectiveness of medicine]</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not stop using this medicine suddenly (if relevant).</li> <li>• [Insert other relevant key point(s)]</li> </ul>
<b>[Other relevant subheading(s)]</b>	<ul style="list-style-type: none"> <li>• [Note: this refers to any condition-specific or medicine-specific subheading(s) as per the full CMI.]</li> <li>• [Insert other relevant key point(s)]</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Insert relevant information regarding any warnings to consider before driving or operating machinery</li> <li>• [Insert other relevant key point(s)]</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• Insert relevant statement regarding drinking alcohol while using the medicine</li> <li>• [Insert other relevant key point(s)]</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Insert storage details, in particular any formulation-specific storage details e.g. refrigerate do not freeze</li> <li>• [Insert other relevant key point(s)]</li> </ul>

For more information, see Section 5. [What should I know while using \[insert medicine\]?](#) in the full CMI.

#### 6. Are there any side effects?

[Include statement of common side effects, and serious side effects in particular that need to be noted.]

For more information on these side effects and what to do if you have any side effects, see Section 6. [Are there any side effects?](#) in the full CMI.

[medicine name]\*

1

## [medicine name]\* (phonetic pronunciation – optional)

Active ingredient(s): [medicine active ingredient(s)] (phonetic pronunciation – optional)

### Consumer Medicine Information (CMI)

This leaflet provides important information about using [medicine name]. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using [medicine name].

Where to find information in this leaflet:

1. [Why am I using \[medicine name\]?](#)
2. [What should I know before I use \[medicine name\]?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use \[medicine name\]?](#)
5. [What should I know while using \[medicine name\]?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

#### 1. Why am I using [medicine name]?

[medicine name] contains the active ingredient [insert active ingredient]. [medicine name] is [insert therapeutic class and explanation].

[medicine name] is used to [insert indication].

#### 2. What should I know before I use [medicine name]?

Warnings

Do not use [medicine name] if:

- you are allergic to [active ingredient], or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- [insert other relevant contraindications].

Check with your doctor if you:

- have any other medical conditions (list any notable ones for the medicine / medical condition here)
- take any medicines for any other condition
- [insert specific precautions relevant to the medical condition].

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. [Are there any side effects?](#)

[medicine name]\*

2

#### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.  
[Include any other relevant pregnancy information specific to the medicine].

#### [Relevant condition-specific or medicine-specific subheading(s)]

- This refers to any medical condition-specific, medicine-specific, and/or age-specific subheading(s) relevant for inclusion for certain categories/groups of users, as applicable to the medicine.

#### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

[Options here include either:

- subdividing and listing the medicines depending on the nature of their interaction – an example of this is included below, or;

- tabulating these medicines that have been grouped according to the nature of their interaction, or;

- if there is only one list of medicines, then ensuring that the information is presented consistently.]

Some medicines may interfere with [medicine name] and affect how it works.  
[Include an explanation of the nature of the interaction where possible] e.g.

Medicines that may **increase** the effect of [medicine name] include:

- [list medicines as appropriate]

Medicines that may **reduce** the effect of [medicine name] include:

- [list medicines as appropriate]

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect [medicine name].



#### 4. How do I use [medicine name]?

##### How much to take / use

- [Include relevant dosage information]
- Follow the instructions provided and use [medicine name] until your doctor tells you to stop.

##### When to take / use [medicine name]

- [medicine name] should be used [insert as relevant].

##### How to [insert appropriate verb] [medicine name] (relevant for devices)

- [Insert relevant step-by-step instructions / considerations for device use]

Any external links to further sources (e.g. instructional videos / diagrams for device use) should be highlighted for ease of access. This will also help to distinguish external links from internal document section links.

##### If you forget to use [medicine name]

[medicine name] should be used regularly at the same time each day [week or month]. If you miss your dose at the usual time, [insert appropriate explanation].

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose you missed.

- [Include explanation of what "almost time for your next dose" refers to for the specific medicine where possible e.g. oral contraceptives]
- [Include any other medicine-specific action and advice re missed dose, as appropriate]

##### If you use too much [medicine name]

If you think that you have used too much [medicine name], you may need urgent medical attention.

##### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

#### 5. What should I know while using [medicine name]?

##### Things you should do

[Include relevant action(s) and explanation(s)]

##### Call your doctor straight away if you:

- [include relevant statements re monitoring of the condition and relevant action(s) to be taken]
- [include relevant statement(s) re action to be taken if the condition worsens / does not improve]

Remind any doctor or dentist you visit that you are using [medicine name].

##### Things you should not do

- Do not stop using this medicine suddenly (if relevant).
- [include any other relevant action(s)]

##### [Relevant condition-specific or medicine-specific subheading(s)]

- Some medicines may require additional subheading(s) relevant to monitoring the condition and actions to be taken while on the medicine e.g. bleeding risk with antiplatelets / hypoglycaemia and what to do.

##### Driving or using machines

Be careful before you drive or use any machines or tools until you know how [medicine name] affects you.

[medicine name] may cause dizziness in some people (or insert relevant information, as appropriate).

##### Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may [insert effect relevant to use of the medicine].

##### Looking after your medicine

- [include device-specific storage information]
- [include storage information] e.g.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

##### When to discard your medicine (as relevant)

[Include any specific information re discarding the medicine e.g. 28 day expiry from date of first use].

##### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

#### 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

##### Less serious side effects

Less serious side effects	What to do
[Grouping 1 as per effect on body e.g. bleeding-related]: • [list as appropriate]	Speak to your doctor if you have any of these less serious side effects and they worry you. [insert appropriate action]
[Grouping 2 as per effect on body]: • [list as appropriate]	

##### Serious side effects

Serious side effects	What to do
[Grouping 1 as per effect on body e.g. bleeding-related]: • [list as appropriate]	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.
[Grouping 2 as per effect on body]: • [list as appropriate]	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

##### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

#### 7. Product details

This medicine is only available with a doctor's prescription.

##### What [medicine name] contains

Active ingredient (main ingredient)	[insert]
Other ingredients (inactive ingredients)	[insert]

Do not take this medicine if you are allergic to any of these ingredients.

##### What [medicine name] looks like

[medicine name] is... (Aust R XXXXXXX)

##### Who distributes [medicine name]

[insert sponsor name and contact details]

This leaflet was prepared in [insert month and year].



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Therapeutic Goods Administration